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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,383	11/29/2001	Karl R. Leinsing	IVACP 56075	6973

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EXAMINER

KEASEL, ERIC S

ART UNIT	PAPER NUMBER
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3754

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/998,383

Applicant(s)

LEINSING ET AL.

Examiner

Eric Keasel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34-44 is/are allowed.
- 6) ☒ Claim(s) 1-5, 12-21, 28-33 and 45-49 is/are rejected.
- 7) ☒ Claim(s) 6-11 and 22-27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 Nov 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 12-14, 18-21, 28-30, and 45-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Mayer (US Patent Number 5,820,601).

Mayer discloses a connector for controlling the flow of fluid, the connector having an internal fluid passageway by which fluid may flow through the connector, the connector comprising: a housing (16) having a first port (28) and a second port (46), the first port being adapted to receive a blunt cannula (15) and the second port adapted for fluid communication with a fluid conduit (12); and a movable element (60, 86, 88) positioned within the housing, the movable element having a first position at which the movable element blocks fluid flow through the housing (see Fig. 3) and a second position at which the movable element permits fluid flow through the housing (see Fig. 4), the movable element comprising: a head (64) defining a bore (80) forming a part of the fluid passageway through the connector, the head being configured such that when the movable element is in the second position (Fig. 4), the bore self-opens to permit fluid flow, the head being further configured such that when the moveable element is in the first position (Fig. 3) the bore moves to a closed configuration preventing fluid flow; a

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compressible section (70) defining an inner conduit forming a part of the fluid passageway through the connector, the inner conduit having a width moveable between a first width (see Fig. 3 where the proximal portion of the housing 20 compresses the section) and a second width (see Fig. 4 where the compressible section is not constrained by the housing), the compressible section being configured so that when the moveable element is in the second position the compressible section self-expands so that the inner conduit has the second width, the inner conduit being further configured so that when the moveable element is in the first position the inner conduit moves to the first width, wherein the first width is smaller than the second width; and wherein the inner conduit is configured such that fluid may continuously flow through the entire inner conduit when the movable element is in the second position; further comprising a support tube (40) having opposing ends, the support tube defining a lumen (56) extending between the opposing ends, one end being in fluid communication with the second port and the lumen forming a part of the internal fluid passageway through the connector; wherein the housing includes a narrowed region (the unnumbered region inside the central bore with the most narrow diameter) adjacent the first port, the head of the movable element being located in the narrowed region when the movable element is in the first position (Fig. 3), the narrowed region being dimensioned so as to cause the bore of the head to close; wherein the housing includes a constricted region (unnumbered region below the narrowed region), the compressible section being located in the constricted region when the movable element is in the first position (see Fig. 3), the constricted region being dimensioned so as to cause the width of inner conduit of the compressible section to move to the first width; wherein the compressible section is connected to the head; and the moveable element further comprises a spring section (96) connected to the

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compressible section, the spring section being adapted to urge the movable element to the first position at which the compressible section is placed within the constricted region. Mayer also discloses the corresponding method associated with the use of the connector in combination with a blunt cannula. Re claims 2, 3, 19, 20, 46, and 47, Mayer discloses both variations wherein the second volume (in the second position) is larger than the first volume (in the first position) or the second volume is the same as the first volume so that the fluid passage creates a zero or positive pressure to avoid blood being drawn into the tube (see column 10, lines 13-64).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 15-17 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer as applied to claims 1, 14, 18, and 30 above, and further in view of Doyle (US Patent Number 6,029,946).

Re claims 16, 17, 32, and 33, Mayer fails to disclose the compressible section comprising a plurality of relatively flexible membrane elements and a plurality of relatively stiff wall elements, the membrane elements connecting together adjacent edges of the wall elements; wherein the membrane elements are adapted to fold radially inwardly when the inner conduit has the first width. Doyle discloses an embodiment (see Fig. 7) in a similar connector that has a plurality of relatively flexible membrane elements (58) and a plurality of relatively stiff wall elements (the thicker, stiffer sections between the grooves 58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the grooves of Doyle (creating relatively flexible and stiffer elements in the compressible section) with the connector of Mayer in order to permit bellowing or folding of the section as the connector is moved to the first position as taught by Doyle (see column 6, lines 43-47).

Re claims 15 and 31, Mayer discloses the head and compressible sections as being integral but fails to disclose the head, compressible section, and the spring section as being integrally molded. Doyle discloses the head (20), compressible section (unnumbered), and spring section (18) as being integrally molded. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have formed the head, compressible section, and spring section of Mayer as a single, integrally molded part as taught by Doyle in order to reduce the number of parts thus making a simpler design with less small parts to lose during the manufacturing process.

Double Patenting

5. Applicant is advised that should claim 18 be found allowable, claim 4 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Allowable Subject Matter

6. Claims 34-44 are allowed.

7. Claims 6-11 and 22-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

8. Applicant's arguments filed 29 Dec 2003 have been fully considered but they are not persuasive.

Applicant argues that the claimed device requires that bore to “self open” when moved to the second position. Applicant indicates that this “self opening” is caused when the male cannula is inserted into the connector (see the last sentence on page 2). Applicant then argues that Mayer's bore doesn't “self open” because “other devices” (e.g. a male cannula) cause the

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opening of the bore. This argument has no merit because the connector of Mayer works in exactly the same manner as the connector of applicant.

Applicant argues on page 4 that the inner conduit of the compressible section of Mayer does not allow for fluid flow. However, when comparing Mayer (Fig. 4) with applicant's Figs. 10 and 12, it is clear that both devices work in exactly the same manner. Therefore, applicant's argument has no merit.

Applicant also does not argue the double patenting objection of claims 18 and 4.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

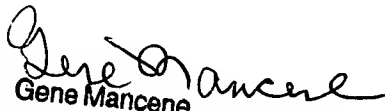
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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Keasel whose telephone number is (703) 308-6260. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gene Mancene can be reached on (703) 308-2696. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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8 Feb 2004


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